EXHIBIT 1

1

COMMONWEALTH OF MASSACHUSETTS

SUFFOLK, SS

SUFFOLK SUPERIOR COURT
CIVIL ACTION NO.: 21-0683E

ROBERT REGONINI,

Plaintiff,

v.

DJD MEDICAL, INC.; and DOMENIC J. DINARDO,

Defendants.

SUFFOLK SUPERIOR COURT
CIVIL CLERK'S OFFICE
2021 MAR 24 A 8:47
MICHAEL JOSEPH DONOVAN
CLERK / MAGISTRATE

COMPLAINT AND DEMAND FOR JURY TRIAL

COMES NOW, Plaintiff, ROBERT REGONINI, by and through the undersigned counsel, and brings this Complaint against Defendants DJD MEDICAL, INC., and DOMENIC J. DINARDO (hereafter collectively referred to as "Distributor", "Distributor Defendants" and/or "Defendants"), and alleges as follows:

SUMMARY OF PLAINTIFF'S ALLEGATIONS

1. This is a lawsuit involving defective metal on metal ("MoM") hip replacement components promoted, marketed, distributed, sold, serviced, and supported by Defendants.

2. The particular components at issue in this case were marketed by Defendants as the "DePuy Pinnacle MoM hip replacement system" (hereafter "DePuy Pinnacle" or "Pinnacle").

3. The Pinnacle Device was manufactured by Johnson & Johnson and its subsidiary DePuy Orthopaedics, Inc.(hereafter, collectively "Johnson & Johnson".) Johnson & Johnson also manufactured another MoM hip implant called the "ASR". Both devices were made with articulating surfaces made of the same or materially similar Cobalt Chrome alloy.

4. Defendants marketed the Pinnacle devices as having significant advantages over other hip devices and hip replacement systems.

5. Defendants marketed MoM hip implants, including the DePuy Pinnacle device, as having significant advantages over other, non-MoM hip replacement systems.

6. Despite Defendants' claims of advantage, both the Pinnacle and the ASR, were defective and unreasonably dangerous for the same reason: the Cobalt Chrome articulating surfaces released toxic heavy metals leading to a high rate of injury as well as revision (replacement) surgery compared with non-MoM implants.

7. In fact, in 2010, Johnson & Johnson were forced to recall their ASR device because of a "higher than expected revision rate" in those devices. Defendants were aware of this recall and assisted in administering it.

8. Following the ASR Recall, and instead of warning of the similarities between the articulating surfaces of the ASR and Pinnacle implants and outcomes in both sets of patients, Defendants attempted to distinguish the Pinnacle from the ASR based upon factors that did not weigh on the actual clinical risks of the toxic heavy metal poisoning.

9. Defendants played an integral role in the omissions and misinformation that resulted in the orthopedic community and Plaintiff's surgeon, in particular, utilizing the Pinnacle.

10. Pinnacle Devices release toxic heavy metals into hip implant recipients' tissue, system, and bloodstream.

11. Defendants are and were aware the metal released from Pinnacle Devices result in unreasonably high rates of negative clinical outcomes, including:

a. elevated levels of cobalt and chromium;
b. tissue death;
c. bone death;
d. loosening;

e. pseudotumors;
f. etc.

12. Defendants are and were aware that these negative clinical outcomes:

a. manifest in severe pain and limitations on mobility;
b. are progressive in nature such that the impact worsens with time and exposure;
c. represent an unreasonable risk of harm to patients;
d. results in a higher than expected rate of failure necessitating additional surgeries to replace failed implants;
e. lead to injuries which can persist even beyond the removal of the failed implants.

13. Plaintiff was implanted with the Pinnacle and has suffered substantial injuries and damages in excess of $75,000.00 due to the defects and unreasonable danger from the device.

PARTIES, JURISDICTION AND VENUE

14. Plaintiff, ROBERT REGONINI, is a resident of Worcester County, Massachusetts.

15. Defendant DJD MEDICAL, INC., is a corporation organized and existing under the laws of the Commonwealth of Massachusetts. Its principal place of business is 90 Hudson Road Canton, MA 02021, and conducts business throughout New England including the Commonwealth of Massachusetts.

16. From 2000 to present, DJD MEDICAL, INC., was the exclusive distributor for the Johnson & Johnson's hip implants, including the DePuy Pinnacle and ASR, in the Commonwealth of Massachusetts.

17. DJD MEDICAL, INC., knew or should have known in-depth information regarding the DePuy Pinnacle product, including, without limitation, the purpose, design, intended use, marketing, surgical technique, risks, benefits, and product performance, among other things.

18. As the exclusive distributor for the Commonwealth of Massachusetts, DJD MEDICAL, INC. was a lucrative business that derived substantial amounts of money from commissions on sales and sales growth incentives within its assigned territory.

19. DOMENIC J. DINARDO, at all times relevant to this complaint, is and was a citizen of the Commonwealth of Massachusetts residing at 22 Liberty Dr. Unit 2G Boston, MA 02210-1249.

20. From 2000 until present DOMENIC J. DINARDO has had the exclusive contract with Johnson & Johnson and its subsidiaries through which he and his company DJD MEDICAL, INC. served as the exclusive distributor for the DePuy Pinnacle in the Commonwealth of Massachusetts.

21. As such, DJD MEDICAL, INC. and DOMENIC J. DINARDO, were responsible for informing & educating medical providers, marketing, selling, facilitating distribution of product to, servicing and supporting Plaintiff's orthopedic surgeons and the Pinnacle hip replacement at issue in this matter.

22. On information and belief, since 2000, Defendants contracted with Johnson & Johnson and its DePuy subordinates for the facilitation of distribution, sales, marketing to medical providers, informing & educating medical providers, servicing and support of DePuy Pinnacle hip replacements implanted in Massachusetts patients, such as the Plaintiff in this matter.

23. Defendants were responsible for informing, educating, marketing, selling, facilitating distribution of product to, servicing and supporting Plaintiff's orthopedic surgeons regarding its product portfolio and, in particular, the Pinnacle hip replacement at issue in this matter.

24. Importantly, this knowledge was not simply the result of information provided by Johnson & Johnson. Instead, much of the knowledge Distributor Defendants gained and shared about hip implants, including the DePuy Pinnacle, was the result of independently gained knowledge and direct communication between the orthopedic community and Defendants.

25. To be clear, Defendants were not simply a mouthpiece for Johnson & Johnson. Defendants would attend conferences and workshops held by a variety of professionals and gain knowledge from sources independent of Johnson & Johnson. This knowledge was utilized by Distributor Defendants during their direct contacts with the orthopedic community, including with Plaintiff's surgeon.

26. Importantly, Defendants attended most—if not all—surgeries at which the products in their portfolio were implanted in the geographical region over which they were responsible. This gave Defendants knowledge regarding the performance of those products during surgery and instruments utilized to implant them, as well as interactions with those surgeons, which were independent from the information in Johnson & Johnson's possession.

27. Most importantly, Defendants and/or their sales representatives attended numerous surgeries in which an ASR or Pinnacle device was revised due to a metal reaction. This means that Defendants had direct and independent knowledge regarding failures of Johnson & Johnson's MoM implants, including the ASR and Pinnacle, which is at issue here. They were direct witness to failures caused by reactions to toxic heavy metals.

28. Defendants were required to inform Johnson & Johnson within 48 hours of each occasion where they came to know that an ASR or Pinnacle implant was revised.

29. This was part of the Johnson & Johnson's requirement to perform post-market surveillance on their products.

30. Upon information and belief, Defendants failed to report to Johnson & Johnson regarding each such revision of which Defendants became aware.

31. This direct and independent knowledge regarding the failed MoM implants meant that Defendants knew or should have known that the Cobalt Chrome articulating surfaces, utilized

in both the ASR and the Pinnacle, represented an unreasonable danger to patients and that the marketing materials provided to them by the Johnson & Johnson did not adequately inform the public and orthopedic community regarding these dangers.

32. In the course of executing their job duties, Defendants not only shared information sourced from Johnson & Johnson which Defendants knew or should have known was materially false, they *omitted* material information in their independent possession regarding the known dangers of the MoM implants which they sold, including the Pinnacle.

THE PINNACLE DEVICE

33. The Pinnacle Device was developed for the purpose of reconstructing diseased human hip joints from conditions such as osteoarthritis, rheumatoid arthritis, avascular necrosis (AVN), and fracture among other degenerative conditions.

34. The hip joint connects the femur bone of a patient's leg to the patient's pelvis. The hip joint is like a ball in a socket. The socket portion of the hip is called acetabulum. The femoral head at the top of the femur bone rotates within the acetabulum.

35. The Pinnacle Device includes four components: 1) the metal femoral stem, which is inserted inside the femur bone, 2) the cobalt chrome metal alloy femoral head (or ball), which connects to the top of the stem and then makes contact with, 3) the liner, which is attached to the interior portion of the, 4) metal acetabular cup (socket). The acetabular cup, or socket, is comprised of a titanium metal alloy on its outer shell. Either a plastic, ceramic, or cobalt-chromium metal alloy liner is then placed on the inside of the acetabular cup. The metal femoral head articulates against the liner.

36. The cobalt-chrome metal alloy liner is branded as the "Ultamet" liner. The Pinnacle with an Ultamet liner is a "metal-on- metal" device because both articulating surfaces - the femoral

head (ball) and acetabular liner (socket) - are made of cobalt-chromium metal. For the purposes of this complaint, reference to the Pinnacle device, generally, is a reference to the Pinnacle device where it is utilized with an Ultamet liner.

37. Defendants focused their marketing strategy to cater to younger and more active patients. For example, Mike "Coach K" Krzyewski, coach of the US Olympic Basketball team and the Duke University men's basketball team, was a celebrity spokesperson for the Pinnacle. Defendants disseminated marketing materials showing an active "Coach K" on a basketball court. Other materials showed a hip implant recipient using an elliptical machine. Additional marketing materials claimed, "Imagine going for a bike ride, playing a doubles tennis match or just climbing the stairs. Thanks to DePuy Orthopaedics' hip replacements, more and more people are getting back to feeling like themselves and moving more naturally than they ever thought possible."

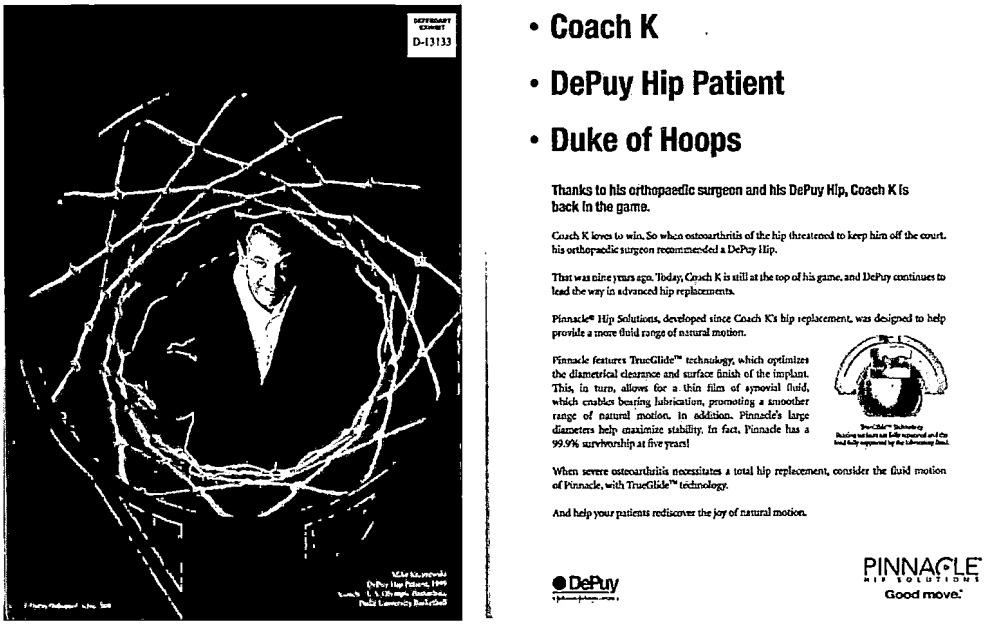
38. Additionally, defendants marketed the Pinnacle Device as

a. "uniquely designed to meet the demands of active patients like you" and disseminated advertisements with pictures of a young woman trying on hiking boots in an athletic shoe store;

b. a superior device featuring TruGlide technology, allowing the body to create a thin film of fluid lubrication between surfaces, which enables "a more fluid range of natural motion;"

c. the best surgical option that "recreates the natural ball-and-socket joint of your hip, increasing stability and range of motion."

d. having "99.9% survivorship at five years!"



39. Defendants are and were aware that Pinnacle Devices had a higher than expected rate of failure and that survivorship with these devices did not reach 99.9% as they claimed.

40. The Pinnacle Device with an Ultamet liner is ultimately defective as it causes release of toxic heavy metals due to the articulation of two cobalt chrome metal alloy surfaces against each other.

41. This process is progressive, with greater metal release over time and increasing clinical reaction. Unfortunately, the toxic heavy metals result in severe injury to the hip joint as well as various systemic maladies.

42. This can include high metal levels, metallosis, pseudotumors, infection, loosening, tissue death, bone death, neurological issues, and many other problems which present with symptoms of pain and loss of function. If the implants are not removed early enough, the effects can be irreversible and permanent.

43. The FDA has received thousands of adverse event reports regarding problems associated with, or attributed to, the Pinnacle.

44. A number of governmental regulatory agencies have recognized the problems caused by metal-on-metal implants, including the ASR and Pinnacle Device. For instance, The Medicines and Healthcare Products Regulatory Agency ("MHRA") in Britain investigated Defendants' metal-on-metal total hip replacement system after receiving widespread reports of soft tissue reactions and tumor growth in thousands of patients who had received these implants. MHRA has required physicians to establish a system to closely monitor patients known to have metal-on-metal hips by monitoring the cobalt and chromium ion levels in their blood and to evaluate them for related soft tissue reactions.

45. Similarly, the Alaska Department of Health recently issued a bulletin warning of the toxicity of Defendants' metal-on-metal total hip replacement systems. The State of Alaska, like the MHRA, identified the need for close medical monitoring, surveillance and treatment of all patients who had received these and similar metal-on-metal implants.

46. Despite a recall of their other MoM device, the ASR, and knowledge that the Pinnacle represents a similar unreasonable risk of harm to patients, Defendants continue to misrepresent the Pinnacle as a high-quality, safe and effective hip replacement product.

DEFENDANTS WERE CRITICAL COGS IN THE PINNACLE OMISSION AND MISINFORMATION WHEEL

47. Johnson & Johnson utilized local distributors to directly market their products to the medical community within each distributor's geographical region.

48. These distributors, including Defendants, and their sales representatives formed close relationships with their surgeons in order to gain the surgeons' trust regarding the distributor and sales representatives claims about the products.

49. In many situations, these distributors, including Defendants, and their sales representatives served as either the surgeons' primary or even only source of information regarding Johnson & Johnson hip implants, including the Pinnacle and ASR.

50. Johnson & Johnson contracted with Defendants to hire, train, and supervise sales representative agents to educate the orthopedic community in Defendants' territory, including Plaintiff's orthopedic surgeon, regarding the claimed advantages of the Pinnacle hip replacement, answer any questions Plaintiff's orthopedic surgeon had regarding the products, assist Plaintiff's orthopedic surgeon at surgery regarding the products, sell the products to Plaintiff through Plaintiff's orthopedic surgeon agent, and service and support the Pinnacle hip replacement after the surgery.

51. Defendants and their sales representatives were required by Johnson & Johnson to undergo training regarding hip replacements generally and the Pinnacle Device specifically.

52. Defendants and their sales representatives served as the principal conduit by which surgeons receive information about the Pinnacle Device.

53. Defendants and their sales representatives were trained on how to promote the Pinnacle Device; this includes but is not limited to surgical instruments, surgical technique, product design, pre-surgical templating, component selection, risks, benefits, and sales strategies.

54. Defendants' sales representatives were trained on how to be of value in the operating room. Distributor Defendants sales representatives were expected to be able to train their surgeons on how to utilize the surgical instruments to implant the Pinnacle and ASR.

55. In fact, their sales representatives were trained to be active participants in the surgeries to implant the products they sold. They would attend most, if not all, surgeries and be present in the operating room in order to assist the surgeons and surgical staff during each surgery.

56. The sales representatives were expected to assist surgeons in pre-op planning of both simple and complex surgical cases; identify competitive advantages within the DePuy product portfolio; demonstrate how to template, plan and consult on product options for primary and revision scenarios.

57. Defendants and their sales representatives were also trained on how to diminish and minimize surgeon concern regarding the ASR and Pinnacle implants. This was done in an effort to increase sales of these products despite valid safety concerns.

58. Defendants assisted in the 2010 recall of the ASR, particularly as it related to the medical community in their territory.

59. Thereafter, utilizing both information provided to them by the Johnson & Johnson as well as information Defendants and their sales representatives independently gained through discussions with medical professionals, lectures, medical reports, and attendance at surgeries of failed MoM implants, Defendants unreasonably distinguished the Pinnacle from the ASR to medical professionals in their territory in an effort to continue to profit from the sale of Pinnacle implants.

DEFENDANTS WORKED DIRECTLY WITH PLAINTIFF'S SURGEON REGARDING PLAINTIFF'S SURGERY

60. Prior to Plaintiff's implant and revision surgeries, Defendants knew or should have known of the unreasonable dangers posed by the metal on metal Pinnacle hip replacement.

61. Defendants and their sales representatives were responsible for answering any questions or concerns Plaintiff's orthopedic surgeon had regarding the Pinnacle hip.

62. Prior to Plaintiff's surgery, Defendants and/or their sales representatives provided information to Plaintiff's orthopedic surgeon regarding the Pinnacle. This included information intended first to ensure Plaintiff's surgeon utilized the Pinnacle over any competitor's products.

63. Unfortunately, this meant that Defendants provided false information regarding the purported benefits of the Pinnacle as well as omitting critical information regarding its risks in an effort to profit from the sale of the implant.

64. In preparation for Plaintiff's implant surgery, Plaintiff's orthopedic surgeon contacted Defendants to notify them of the need for hip replacement components and instruments. Additionally, Defendants met with Plaintiff's orthopedic surgeon to template the surgery and confer with the surgeon regarding appropriate sizes, parts, instruments, and techniques.

65. Defendants' sales representative selected and provided the specific components and instruments to be available during the surgery and delivered them to the operating room where Plaintiff's surgery took place.

66. During Plaintiff's surgery, Defendants' sales representative was present in the operating room to provide the inventory of implant components as well as surgical instruments to utilize during implantation and any other assistance as requested by Plaintiff's surgeon and surgical staff.

67. At all times relevant to this Complaint, Plaintiff's orthopedic surgeon, nurses and hospital staff relied on information and assistance from Defendants and their sales representatives.

68. The above communications and information were provided to Plaintiff's orthopedic surgeon with the intended purpose of convincing and inducing Plaintiff's orthopedic surgeon to use the metal on metal Pinnacle hip replacement instead of one of the competing hip replacements.

69. Defendants and their sales representatives' communications to the orthopedic community, including Plaintiff's surgeon, were in no way limited to the information provided on the Pinnacle hip packaging or labeling.

FACTUAL ALLEGATIONS OF PLAINTIFF ROBERT REGONINI

70. At all times relevant to this Complaint, Plaintiff, is and was a citizen of the Commonwealth of Massachusetts.

71. Plaintiff suffered from right hip osteoarthritis leading to a right total hip replacement.

72. Defendants' defective device was placed into the stream of interstate commerce and Plaintiff was implanted with the metal on metal Pinnacle hip replacement on September 6, 2008, at UMASS Memorial Health Care in Worcester, MA.

73. The defective device reached Plaintiff without substantial change in its condition when it left the possession of Defendants and was used in the matter for which it was intended.

74. The defective device was defective and unreasonably dangerous when it was placed into the stream of commerce by Defendants.

75. Over the ensuing years, Plaintiff unknowingly suffered heavy metal poisoning from the toxic heavy metals released by the hip replacement, resulting in injury and requiring surgery to remove the defective hip replacement.

76. On June 26, 2020, Plaintiff was forced to undergo surgical removal of the defective Pinnacle hip replacement due to toxic heavy metal poisoning at Saint Vincent Hospital in Worcester, MA.

77. Plaintiff continues to undergo the slow process of recovery from the surgery that would not have been necessary but for the defective nature of the Pinnacle hip replacement.

78. As a direct and proximate result of Defendants placement of the defective device into the stream of commerce, Plaintiff was required to undergo surgical removal of the defective device, now has a hip replacement with decreased longevity, and suffered injuries, including but

not limited to significant pain, permanent tissue destruction, irrigation and debridement of brown fluid and tissue, metal wear, adverse tissue reaction, and toxic heavy metal poisoning.

79. Plaintiff expects to continue suffering such injuries in the future as a result of the injuries received from the Pinnacle.

80. As a direct and proximate result of the defective Pinnacle, Plaintiff incurred medical expenses and expects to incur additional medical expenses in the future.

81. As a direct and proximate result of the defective Pinnacle, Plaintiff incurred lost earning potential, income, and earnings.

82. As a direct and proximate result of the defective Pinnacle, Plaintiff experienced emotional trauma and distress and is likely to experience emotional trauma and distress in the future.

COUNT I - NEGLIGENCE
(All Defendants)

83. Plaintiff re-alleges and incorporates by reference paragraphs 1-82 above as if fully stated herein.

84. At all times material hereto, the Defendants marketed, promoted, advertised, sold, distributed, serviced, and supplied the Pinnacle for implantation into the bodies of consumers such as and including Plaintiff, to both physicians and consumers, including to Plaintiff and Plaintiff's surgeon.

85. As a result, Defendants had a duty to perform each of these functions reasonably and with reasonable and due care, for the safety and well-being of patients in whom the devices would be implanted.

86. Sales representatives working for the Defendants were responsible for educating and continuously guiding surgeons regarding the proper patient selection, surgical planning,

component selection, surgical technique, and post-surgery follow-up.

87. As a result, Defendants has a duty to ensure their sales representatives had knowledge akin to an expert related to the Pinnacle hip system.

88. Surgeons, such as Plaintiff's surgeons, reasonably relied upon Defendants to properly perform these functions and Defendants had a duty to perform such functions and to protect Plaintiff from injury.

89. Defendants failed to use reasonable and due care for the safety and well-being of those in whom the device would be implanted, and is, therefore, negligent to wit:

a. Defendants failed to adequately warn consumers and surgeons that the device would corrode, erode, deteriorate, fret, and induce severe metal toxicity in the patient;
b. Defendants failed to adequately educate themselves of the risks associated to the Pinnacle hip system and failed to stay abreast of the growing evidence of device dangers;
c. Defendants negligently misrepresented the degree of testing of the device, effectively hiding the fact that when manufactured and marketed, patients became, in essence, Defendants' first clinical trial;
d. Defendants made affirmative representations that the device would not fret, generate excessive metal debris, or corrode in the human body. These representations were false and misleading to both physicians and the consumer;
e. Defendants utilized representations that Defendants knew or should have known were false, creating in the minds of both surgeons and consumers, that the device would not cause metal toxicity;
f. Defendants specifically marketed the device as a safe alternative to metal-on-metal bearing devices that had been widely publicized as capable of causing premature failure due to heavy metal toxicity, including Johnson & Johnson's ASR device; and
g. Defendant became aware of adverse events regarding the product, including but not limited to tissue reaction and/or necrosis and/or infection, metallosis, and pseudotumor formation, yet continued to provide the product for implantation in unknowing patients by unknowing surgeons.

90. Plaintiff suffered actual injury and loss because of said breach.

91. The conduct described above exhibits Defendants' failure to exercise reasonable care. It was foreseeable that such negligence would lead to premature device failure, as well as

severe, debilitating injuries that were permanent.

92. As a direct and proximate result of Defendants' negligence, Plaintiff suffered failure of the Defective Device, as described in paragraphs 71-82 above, including but not limited to severe physical pain and suffering, emotional distress, mental anguish, loss of the capacity for the enjoyment of life, medical and nursing expenses, and surgical expenses. These damages have occurred in the past and will continue into the future.

WHEREFORE, Plaintiff respectfully requests that he be granted relief against Defendants as contained in the Prayer for Relief.

COUNT II –BREACH OF EXPRESS WARRANTY
(All Defendants)

93. Plaintiff re-alleges and incorporates by reference paragraphs 1-92 above as if fully stated herein.

94. Defendants sold and Plaintiff purchased the products at issue in this Complaint.

95. Defendants expressly warranted that the Pinnacle was reasonably fit for its intended purpose as a hip replacement system. These warranties included, without limitation, the allegations above (*see* ¶¶ 4-5, 40-41, and 64-65) as well as the following:

a. The Pinnacle produced less wear than competing devices;
b. The Pinnacle bearing surfaces were all carefully tested;
c. The Pinnacle was a clinically safe system;
d. The Pinnacle did not exhibit high rates of revisions;
e. Fluid film lubrication would prevent contact of the ball and cup during articulation.

96. The representations set forth above contained or constituted affirmations of fact or promises made by the seller to the buyer which related to the goods and became part of the basis of the bargain creating an express warranty that the goods shall conform the affirmations of facts or promises.

97. Plaintiff was a reasonably foreseeable user of the Pinnacle.

98. Such representations by Defendants were meant to induce Plaintiff, through Plaintiff's physician, to purchase the products at issue in this Complaint.

99. The products at issue in this Complaint did not conform to the warranties and representations made by Defendants.

100. Defendants breached the express warranties it provided with the products at issue in this Complaint.

101. As a direct and proximate result of the breach of the warranties regarding the Pinnacle, Plaintiff suffered the injuries as described in paragraphs 71-82 above.

WHEREFORE, Plaintiff respectfully requests that he be granted relief against Defendants, as contained in the Prayer for Relief.

COUNT III — BREACH OF IMPLIED WARRANTY OF MERCHANTABILITY
(All Defendants)

102. Plaintiff re-alleges and incorporates by reference paragraphs 1-101 above as if fully stated herein.

103. At all times material hereto, the Defendants marketed, promoted, advertised, sold, distributed, serviced, supplied, and placed into the stream of commerce in Massachusetts, the Pinnacle for implantation into the bodies of consumers such as and including Plaintiff, to both physicians and consumers, including to Plaintiff and Plaintiff's surgeon.

104. The Pinnacle hip system marketed, promoted, advertised, sold, distributed, serviced, and supplied by Defendants were expected to and did reach Plaintiff in substantially the same condition they were in when originally marketed, distributed, and sold by Defendants.

105. Defendants warranted that the Pinnacle was merchantable and reasonably fit for its intended purpose as a hip replacement system. However, the Pinnacle hip was and remains

defective and unreasonably dangerous. These warranties included, without limitation, the allegations above (*see* ¶¶ 4-5, 40-41, and 64-65) as well as the following:

a. The Pinnacle produced less wear than competing devices;
b. The Pinnacle bearing surfaces were all carefully tested;
c. The Pinnacle was a clinically safe system;
d. The Pinnacle was stronger and designed to last longer than competing devices;
e. The Pinnacle was designed and appropriate for younger more active patients;
f. The Pinnacle did not exhibit high rates of revisions;
g. Fluid film lubrication would prevent contact of the ball and cup during articulation;
h. The Pinnacle was a safer alternative to metal on plastic hips using ultra-heavy duty plastic liners.

106. The representations set forth above were implied in marketing and promotional materials, and on information and belief were shared with surgeons by Defendants and constitute implied affirmations of fact or promises made by the seller to the buyer which related to the goods creating an implied warranty that the goods shall conform the affirmations of facts or promises. These implied warranties were relied on by Plaintiff in choosing to move forward with implantation of the Pinnacle hip.

107. Plaintiff was a reasonably foreseeable user of the Pinnacle.

108. Defendants expected and intended people, like Plaintiff, to use the Pinnacle hip all the while knowing the produce was defective, unreasonably dangerous, and would cause serious harm.

109. Defendants breached their obligations because the Pinnacle hip system marketed, sold, and distributed by Defendants to Plaintiff, and other members of the public, were defective and unreasonably dangerous to users and consumers, because the Pinnacle hip system released toxic heavy metals into the hip joint and blood of consumers such as Plaintiff.

110. The Pinnacle hip contained insufficient, inadequate, and defective warnings regarding the dangerous risks and reactions associated with the unreasonably dangerous and

defective product, including, but not limited to the risks of heavy metal poisoning and the deleterious effects of metal debris on the hip joint.

111. The foreseeable risks posed by the Pinnacle hip could have been reduced or eliminated by their adoption of a safer, reasonable alternative design.

112. Defendants, the marketers, distributors, and servicers of the Pinnacle hip, were and are held to the level of knowledge of an expert in the field. They have knowledge of the dangerous risks and harms caused by the Pinnacle hip which they failed to protect and warn against.

113. Plaintiff did not have the same knowledge as Defendants.

114. Plaintiff used the Pinnacle for the purpose and in the manner intended by Defendants.

115. Defendant's warranties were part of the basis of the bargain for Plaintiff's purchase of the Pinnacle.

116. Defendants' warranties proved to be untrue. In other words, the Pinnacle was not reasonably fit for the ordinary purposes for which such goods are used and did not meet the expectations for the performance of the product when used in the customary, usual, and reasonably foreseeable manner.

117. Although Defendants knew of the defective nature of the Pinnacle hip, they continued to promote and sell the Pinnacle without providing a safer alternative or adequate warnings and instructions concerning its use. These deliberate actions were taken so as to maximize sales and profits at the expense of the public health and safety, in knowing, conscious, and deliberate disregard of the foreseeable harm caused by this product to Plaintiff and others who were similarly situated.

118. As a direct and proximate result of the breach of the warranties regarding the Pinnacle, Plaintiff suffered the injuries as described in paragraphs 71-82 above.

WHEREFORE, Plaintiff respectfully requests that he be granted relief against Defendants, as contained in the Prayer for Relief.

COUNT IV — NEGLIGENT MISREPRESENTATION
(All Defendants)

119. Plaintiff re-alleges and incorporates by reference paragraphs 1-118 above as if fully stated herein.

120. In the course of their business and business transactions, Defendants supplied false information about the Pinnacle for the guidance of others, including Plaintiff, Plaintiff's orthopedic surgeons, and the medical community prior to and after Plaintiff was implanted with the Pinnacle.

121. Defendants possessed (and possess) superior knowledge about the level of clinical testing and safety of the Pinnacle hip replacement, including the lack of reliable support for representations about the asserted clinical safety and failure rates of the metal on metal Pinnacle hip replacement.

122. Defendants were at all times relevant acting within the scope of their business for their own economic and pecuniary gains.

123. The Plaintiff and his surgeon were not able to discover Defendant's superior and specialized knowledge and experience about metal on metal Pinnacle product complaints, failures and revisions, and their systems for reporting and analyzing the same.

124. Defendants have failed in their duty to disclose known material facts to the Plaintiff and Plaintiff's surgeon regarding the Pinnacle, including but not limited to:

a. Falsely representing the Pinnacle had resolved the metal ion wear problems that

had plagued similar metal-on-metal hip products, including the predicate systems on which it was based, particularly after the 2010 recall of the DePuy ASR.

b. Falsely representing the Pinnacle as reducing wear and providing higher function for patients than other available hip systems.
c. Falsely representing the Pinnacle metal-on-metal bearing system as a lifetime hip product.
d. Falsely representing that the Pinnacle is a safer and stronger alternative when compared with other available hip systems, notwithstanding internal information dating as far back to 1995 to the contrary.
e. Falsely representing that the Pinnacle provided fluid film lubrication.
f. Failing to disclose the clinical significance and safety concerns regarding heavy metal poisoning, notwithstanding notice as early as 2006 from surgeons seeing increased revision rates with the Pinnacle device.
g. Failing to disclose patterns and trends of failure Pinnacle implants. *See also* ¶¶ 4-12, 29-33, and 39-48.

125. The above representations and omissions were material and were made with the intent to persuade and induce Plaintiff, Plaintiff's surgeon, and the medical community to choose and to fail to properly follow-up, with patients, such as and including Plaintiff, regarding the Pinnacle hip replacement system.

126. Defendants made the above representations or omissions knowing the misrepresentations were false or were ignorant of the truth of the assertions.

127. The above representations and omissions are reflected in Defendants' marketing of the Pinnacle product in the Commonwealth of Massachusetts. Defendants directed the aggressive promotion of the Pinnacle products to Massachusetts' orthopedic community through regular conversations, meetings, written publications, brochures, and field communications which reflect the representations and omissions detailed above. Through this marketing effort, Defendants established acceptance of their representations about the Pinnacle product's safety among surgeons in Massachusetts' orthopedic community.

128. Defendants made the above misrepresentations or omissions with the intention and knowledge that their efforts would influence Massachusetts surgeons and consumers in their

decisions to select the Pinnacle hip replacement for surgical implantation in patients.

129. Defendants failed to exercise reasonable care of competence in obtaining or communicating the information to Plaintiff and Plaintiff's orthopedic surgeon.

130. Plaintiff and Plaintiff's orthopedic surgeon justifiably relied upon and were induced to act in reliance on Defendants' misrepresentations or omissions and in fact purchased the Pinnacle based on these misrepresentations or omissions.

131. As a direct and proximate result of the negligently supplied information regarding the Pinnacle, Defendants caused Plaintiff to suffer pecuniary loss and injuries as described in paragraphs 71-82 above.

WHEREFORE, Plaintiff respectfully requests that he be granted relief against Defendants, as contained in the Prayer for Relief.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for judgment against Defendants as follows:

a. Awarding compensatory damages resulting from Defendants' violation of Massachusetts law;

b. Awarding compensatory damages resulting from Defendants breach of warranty and negligence;

c. Awarding actual damages to Plaintiff, incidental to Plaintiff's purchase and use of the Pinnacle Hip System, in an amount to be determined at trial;

e. Awarding pre-judgment and post-judgment interest to Plaintiff as provided by law;

f. Awarding the costs and expenses of their litigation to Plaintiff;

g. Awarding reasonable attorneys' fees and costs to Plaintiff as provided by law; and

h. Granting all such other relief as the Court deems necessary and proper.

DEMAND FOR JURY TRIAL

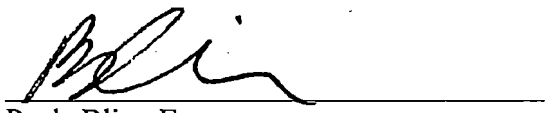
Plaintiff hereby requests a trial by jury of all issues triable by jury.

Dated: March 18, 2021

Respectfully submitted,

PLAINTIFF

By his attorney,



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